REMARKS

Claims 1-7, 11, 14-17 and 19-52 are presently pending. Of these, Claims 46-52 are withdrawn from consideration. Claims 8-10, 12, 13 and 18 are canceled without prejudice. No new matter has been added herewith. The following addresses the substance of the Office Action.

Written Description

Claims 1-9, 11 and 13-45 were rejected under 35 U.S.C. § 112, first paragraph, as failing to meet the written description requirement. The written description rejection relates to the terms "a lectin-interactive agent" and "an immune modulating agent". The Examiner stated that these terms alone are insufficient to describe the genus.

With regard to "a lectin-interactive agent," the Applicant has amended Claim 1 to replace the phrase "lectin-interactive agent" with the phrase "soluble, non-metabolizable carbohydrate or a soluble, non-metabolizable carbohydrate-containing molecule". Such molecules are further limited by reciting that they are selected from the group consisting of molecules that were formerly listed in Claim 8.

With regard to "an immune-modulating agent," the Examiner appears to have overlooked that this term alone is not used to describe the genus. The claim further specifies that the immune modulating agent is selected from the group consisting of an antigen or a part thereof that elicits an immune response against the target antigen, an antigen-binding molecule, and an immune-modulating cell. Thus, the term "immune-modulating agent" is specifically limited to these types of agents. For each type of agent, extensive written description is provided in the specification. For example, the terms "antigen" and "antigen-binding molecule" are specifically defined at paragraphs [0030] and [0031]. All of these types of immune modulating agents are discussed in great detail in the specification (i.e., "antigens," see Section 2.2.1 at paragraphs [0079] to [0101]; "antigen-binding molecules," see Section 2.2.3 at paragraphs [0133] to [0136]; and "immune-modulating cells, see Section 2.2.2 at paragraphs [0102] to [0132]).

The Examiner stated that there is no teaching regarding any structural property which is retained by agents which have the ability to interact with lectin, or agents which can modulate the immune system and "corresponds to at least a portion of" a target antigen. As discussed below, in connection with the first indefiniteness rejection, the Applicant has deleted the phrase "corresponds to at least a portion of". In view of the extensive written description in the specification with regard to "antigen," "antigen-binding molecule" and immune modulating cell,

there is sufficient written support for recitation of "an immune-modulating agent selected from the group consisting of the target antigen, a part of the target antigen that elicits an immune response against the target antigen, an antigen-binding molecule that is immuno-interactive with the target antigen and an immune-modulating cell that modulates an immune response to the target antigen".

In view of the amendments to the claims and the preceding remarks, the claims do not lack sufficient written description. Accordingly, the Applicant respectfully requests that the rejection on the basis of lack of written description be withdrawn.

Indefiniteness

Claims 1-9, 11 and 13-45 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite. In particular, the claims were rejected on the basis that the term "corresponds to at least a portion of the target antigen" is indefinite. The Examiner stated that "a portion of" is indefinite because no minimum value is provided. The Examiner also noted that there was no minimum value for the level of correspondence required. Applicant has deleted recitation of "corresponds to at least a portion of" from the claims, thereby obviating the rejection.

Claim 14 was also rejected under 35 U.S.C. § 112, second paragraph as being indefinite. In particular, Claim 14 was rejected on the basis that the phrase "synthetic or semisynthetic analog" [of lactulose] was unclear. Applicant has deleted the phrase from Claim 14, thereby obviating the rejection.

In view of the amendments to the Claims, the Claims are believed to be in compliance with the requirements of 35 U.S.C. § 112, second paragraph. Accordingly, the Applicant respectfully requests that the rejections be withdrawn.

Anticipation

Figdor et al.

Claims 1-9, 11 and 13-45 were rejected under 35 U.S.C. § 102(b) as being anticipated by Figdor et al. (WO 00/63251). The Examiner concluded that reference discloses a composition comprising a lectin interactive agent (compound that binds C type lectin) and an immune-modulating agent (tumor antigens, infectious disease antigens).

To more clearly distinguish over the cited reference, the Applicant has amended Claim 1 to recite that the composition for modulating an immune response to a target antigen comprises a

soluble, non-metabolizable carbohydrate or a soluble, non-metabolizable carbohydrate-containing molecule. To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed.Cir. 1986). "[A]nticipation requires that all of the elements and limitations of the claim are found within a single prior art reference." *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991). Since Figdor et al. does not teach the use of a soluble, non-metabolizable carbohydrate or a soluble, non-metabolizable carbohydrate-containing molecule, the reference does not anticipate the present claims. Accordingly, the Applicant respectfully requests that the rejection under 35 U.S.C. § 102(b) be withdrawn.

Nedwin et al.

Claims 1-9, 11 and 13-45 were also rejected under 35 U.S.C. § 102(b) as being anticipated by Nedwin et al. (U.S. Patent No. 5,587,460). Nedwin generally relates to a specific 14 kDa mammalian lectin that has beta-D-galactoside binding properties. The Examiner cited this document on the basis that Example 7 discloses a composition comprising a lectin-interactive agent (thiodigalatoside) and an immune-modulating agent (the 14 kDa lectin). Example 7 is repeated below for ease of reference:

EXAMPLE 7

Assay for Beta-galactoside Binding Activity of Lectins

Biological activity of 14 kDa lectin from HL-60 cells, placenta tissue, and *E. coli* cells transfected with lectin cDNA operably linked to a secretion signal was ascertained by agglutination of trypsinized rabbit erythrocytes. As seen in FIG. 12, the top row shows a Concanavalin A control with an agglutination end-point at 1.5 mcg/ml. The lower 6 rows show the three purified 14 kDa lectins incubated with varying concentrations of competing sugars beta-lactose and thiodigalactoside which are known to be potent inhibitors of the 14 kDa placenta lectin. Thiodigalactoside inhibited agglutination of the erythrocytes at concentrations greater than 0.31 mM and beta-lactose inhibited agglutination at concentrations greater than 1.25 mM.

However, lectin is not an immune-modulating agent, as claimed in the present application, because it is neither a) a target antigen, b) a part of the target antigen that elicits an immune

response against the target antigen, c) an antigen-binding molecule that is immuno-interactive with the target antigen, nor d) an immune-modulating cell that modulates an immune response to the target antigen. Hence, the composition disclosed in Example 7 of Nedwin et al. does not anticipate the presently claimed compositions. Moreover, in the presently claimed compositions, the soluble, non-metabolizable carbohydrate or soluble, non-metabolizable carbohydrate-containing molecule blocks the action of the lectin, while the immune-modulating agent stimulates an appropriate immune response without attenuation. In addition, the Applicant notes that the purpose of Example 7 is to test the suitability of lectin in vivo, and therefore does not disclose a method or composition for modulating an immune response as presently claimed.

In view of the amendments to the claims and the foregoing remarks, the Claims are not anticipated by Nedwin et al. Accordingly, the Applicant respectfully requests that the rejection under 35 U.S.C. § 102(b) be withdrawn.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of Applicants' amendments to the Claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: April 15, 2010

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